Thoughts on Food Safety Agency Restructuring in the US

By M J Gilsdorf

With every new food safety recall, demands for a solution to the food safety problem are becoming more vociferous.[1] The proposals for improvements range from restructuring the U.S. Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) to reshaping the food industry so it can better monitor itself. Many seek ways to modernize the systems because food is not processed or distributed in the same ways it was 30 years ago.

Additional safeguarding concerns to food safety are the U.S. consumers growing appetite for imported foods. Americans now consume $70 billion worth of foods from abroad, up from $36 billion just a decade ago[2]. Imported foods make up 13 percent of the typical American diet.[3] The FDA reports that its inspectors sample between 1 and 2 percent of all lines of food being sent to the United States from other countries.[4] Lines of food products are declared by importers on manifests which are all reviewed by FDA, FSIS, and/or Customs and Border Control (CBP) at ports of entry. A line of food product may amount to one box in a shipment up to everything on a cargo ship. Is this procedure adequate to prevent food safety issues from occurring? FDA cannot logistically inspect every line of food product entering the country because there are more than ten million lines food products for the FDA to oversee. Therefore, the FDA and FSIS must sample and inspect based on risk. FDA uses risk-based algorithms to determine which food products to sample. Reviewing how these algorithms function and how they can be improved is something that should be considered.

Current food regulations were adopted as the need arose which has created overlaps and redundancies. Some critics contend that existing regulations cannot guarantee the safety of all foods sold in the United States. I would submit that the agencies and regulations can never guarantee the safety of any food product- they can only manage the risks. My understanding is that the FDA and FSIS are trying to manage the risks based on conscious decisions of what is considered an acceptable/not acceptable risk. Both the FDA and FSIS try to determine the risk of meat and food products by evaluating the disease status of the country of origin, the type of product being imported, past history of the product, etc. Also, both agencies focus on risks associated with bacterial and chemical contamination. However, one of the challenges that both agencies face is the number of registered companies there are to regulate. The FDA has over 300,000 registered companies to regulate[5]. Most of those firms are located in other countries. This is too many firms to effectively obtain a sample from every shipment.

Solutions to the problems of decreasing food contamination and recalls are complex but should center on risk management and closing any gaps that might exists in authorities and oversight. Current discussions include creating a new super food agency that would oversee all food safety issues currently housed in FDA and FSIS and locating this new agency within the Department of

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[1] http://www.ajc.com/health/content/shared-auto/healthnews/fda-/611281.html

[2] http://www.sjhlex.org/11899.cfm, St Joseph Health system

[3] http://www.henryfordhealth.org/159449.cfm

[4] Personal communication from Dr Stephen Sunlof

[5] Personal communication from Dr Stephen Sunlof

Health and Human Services (HHS). Most of the NAFV members I have talked with do not favor this option. A second option is to house the super food agency within USDA and have it managed by food safety professionals. Most of the NAFV members I have talked with favor this option. A third option is to leave FSIS as is and restructure FDA into two divisions, one for food safety and one for drug evaluations, devices, and biologics. This seems to be the most popular option at this time. There are bills being introduced in Congress that address this option, such as HR 875, the Food Safety Modernization Act of 2009. Under this bill, HHS would establish the "Food Safety Administration" and transfer the functions and resources of (1) the Center for Food Safety and Applied Nutrition of the Food and Drug Administration; (2) the Center for Veterinary Medicine of the Food and Drug Administration; and (3) the National Center for Toxicological Research of the Food and Drug Administration. Another bill requires instituting equivalency standards for imported foods and was introduced by Rep. John Dingell, a Michigan Democrat and chairman of the Energy and Commerce Committee. The bill would also limit the number of U.S. ports that foreign foods could enter to only those equipped with FDA laboratories.

In September 2008, the Grocery Manufacturers Association, which represents the nation's top food producers, released a plan that it said was designed to better safeguard food imports.[6] The plan is based on risk management and provides incentives for foreign countries and firms with good safety records. This concept would theoretically allow FDA and FSIS to focus more on products that present the largest risk. I would need to know more about this plan before I could comment on its validity, but I like the concept.

It has been stated that FSIS receives 80 percent of the food safety budget to regulate 20 percent of the food supply and FDA receives 20 percent of the budget to oversee 80 percent of the nation's food. However, these figures by themselves do not present the whole picture. There are underlying differences in risks associated with meat and poultry versus other food products that must be considered. I think it is important for FSIS to maintain a higher level of inspection and sampling on meat and poultry because the potential risks for bacterial and chemical contamination are higher in meat than most other food products.

Ultimately it is the responsibility of the manufacturer to produce safe food. The government's role is to make sure the industry meets their responsibility by following good manufacturing practices and sanitation standard operating procedures. As more companies and countries produce more products, it is critical that better risk based systems be developed and utilized by manufacturers and government agencies. This is more important than centralizing authority into one agency in my opinion.

Another big issue regarding food safety is recall authority. FDA and FSIS do not have recall authority. However, both agencies are able to effectively work with the producer in most instances and ask them to recall products when needed. Therefore, I don't see the need for recall authority in these agencies. More importantly, food safety agencies may need more authority to require that importers put systems in place to ensure food safety. They also need resources to adequately conduct foreign inspections and review other countries' food safety systems based on risk assessments. Please send me your thoughts and comments on these issues. Thanks

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[6] http://www.gmabrands.org/news/docs/NewsRelease.cfm?DocID=1767